



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :)
ATSUO F. FUKUNAGA et al.)
)
Serial No.: 10/777,772) Examiner: Darwin P. Erezo
)
Filed: February 12, 2004) Group Art Unit: 3731
)
Entitled: BREATHING CIRCUITS HAVING) Atty. Docket No.: 10437-69
UNCONVENTIONAL RESPIRATORY CONDUITS)
AND SYSTEMS AND METHODS FOR OPTIMIZING)
UTILIZATION OF FRESH GASES)

Assistant Commissioner For Patents
Washington, D.C. 20231

DECLARATION UNDER 37 CFR § 1.132

Sir:

I, Atsuo F. Fukunaga, M.D., Ph.D., hereby declare the following:

1. I am an inventor of the captioned application.
2. I am a board certified anesthesiologist licensed to practice in the U.S. and Japan. I am professor emeritus of anesthesiology at the University of California, Los Angeles, School of Medicine. I earned my M.D. degree from Toho University School of Medicine in 1963, and my Ph.D. from Tokyo University, School of Medicine in 1972.
3. I have studied and performed research in the field of anesthesiology as well as respiratory care for over 40 years. I have given invited lectures on breathing systems at scientific meetings. I am the inventor of breathing circuits that have been used worldwide and considered to be state of the art, including breathing circuits claimed in patents cited or made of record in this application.
4. As a board certified anesthesiologist and a physician specializing in the practice and teaching of anesthesia and respiratory care, I have regularly used breathing circuits of all kinds,

and I am familiar of the requirements of breathing circuits that enable safe anesthesia and respiratory care. In addition, as a researcher, I have regularly attended scientific meetings related to respiratory care and anesthesia, and I am familiar with breathing circuits that have been used by practitioners.

At X: I have read and am familiar with the above-referenced patent application, the claims of which are rejected in the Office Action mailed February 14, 2007. I have read and am familiar with the scientific articles, patents and other documents cited or made of record in this patent application, as well as other relevant scientific literature in the field of respiratory care and breathing circuits.

5. Claims 4, 5, 8, 9, 11, 12, 16, 18, 20 and 29 were rejected over patent documents "Suzuki" in view of "Clawson". One of ordinary skill in the art of breathing circuits would not be led to modify Suzuki using the teachings of Clawson for numerous reasons. The Suzuki circuit is a fixed length, unitary circuit. Suzuki uses corrugated tubing, which is very different from the pleated tubing used in the present invention; pleated tubing functions very differently from Suzuki's corrugated tubing. Corrugated tubing cannot be axially extended or contracted and it's small, even corrugations are designed merely to add structural strength to help maintain the shape of the tubing. Hence, the flow characteristics and volume of corrugated tubing in a circuit formed thereof are consistent and its performance can be reliably predicted. In contrast, the pleats in a pleated tube radially protrude significantly further into the tube than the corrugations of a corrugated tube, causing significantly different flow patterns and breathing resistance than would be seen in a corrugated tube. The air flow in a pleated tube is even more greatly altered by axially extending or contracting the tube, which alters the flow, resistance and volume of the tube particularly in coaxial circuits.

6. It is critical that in evaluating breathing circuits, it must be kept in mind that the circuits are oxygen and anesthetic gas delivery systems. Small changes in a circuit can lead to significant changes in the amount of gases delivered to a patient, and insufficient delivery of oxygen and/or anesthetic gases. Hence, research on improving breathing circuits shares all of the unpredictability of pharmaceutical research, and even a single change of tubing type or length or the configuration of a breathing circuit is a major modification that requires significant research to establish the

benefit or detriment thereof.

7. Therefore, the discovery I made in developing the present invention is truly surprising; I discovered that a circuit comprising pleated tubing in a unilimb configuration could be reliably used to provide assisted and spontaneous ventilation despite the flow variations inherent in the structure of pleated tubing. I also discovered that by use of a circuit comprising pleated tubing the ratio of gases delivered to a patient versus gases input into the circuit can be adjusted and thereby be optimized. This leads to more accurate delivery of anesthetic gases despite the greater flow disruptions and unpredictability associated with pleated tube use.

8. One of skill in the art of anesthesia knows that it is *a requirement for safe anesthesia* that a circuit permit *spontaneous* and *assisted* ventilation. Clawson's coaxial circuit can not provide spontaneous ventilation and cannot be used in conventional ventilation and anesthesia. Clawson's circuit is designed to provide high frequency ventilation. It includes a narrow tube and nozzle and a complicated manifold with an internal valve; a single extendable breathing tube carries gases from the manifold to a patient fitting (such a tube provides a significant "dead space" and there are many teachings that such a "dead space" at the end of a circuit is not desirable). It is respectfully submitted that one of skill in the art would likely have doubts that Clawson could properly function for its intended purpose as (1) the high pressures required for high frequency ventilation would require tubing with strong and rigid walls (i.e., almost zero compliance) and strongly bonded fittings to prevent detachment under the high pulsed pressures, for which conventional pleated tubing appears insufficient, and (2) the great resistance to flow in Clawson's nozzle would prevent sufficient gas flow to the single breathing tube leading to a patient. Even assuming for the sake of argument that Clawson could work for its intended purpose, it cannot provide spontaneous ventilation due to the nozzle and valve arrangement, and Clawson does not address the important issue of pressure, air flow, resistance to breathing and respiratory rate used in spontaneous ventilation and conventional anesthesia.

9. One of ordinary skill in the art having Suzuki and Clawson before them would have no motivation or suggestion in the references that would encourage them to disassemble Clawson and Suzuki and reassemble selected components from Clawson and Suzuki to form the present invention. There is nothing in Clawson or Suzuki that addresses the critical issue of pressure, air

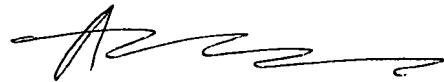
flow, resistance to breathing and respiratory rate sufficiency in using coaxial pleated tubing for providing spontaneous and assisted ventilation. In order to combine these teachings, one of skill in the art must also ignore Clawson's teaching of the desirability of having a single breathing tube (i.e., dead space) between the patient fitting and the narrow nozzle and valve outlet at the end of the coaxial portion of Clawson's device, and overcome the different function, flow and pressure requirements of Clawson's device for its intended purpose versus the requirements of Suzuki. Only with hindsight and having the present patent application showing that coaxial pleated tubes provide sufficient flow for spontaneous and assisted ventilation and other surprising benefits could one of ordinary skill in the art make the combination

10. Furthermore, prior art unilimb circuits, such as Suzuki's circuit, can not achieve the numerous unexpected results and advantages than can be provided by the claimed invention and which are described in the present specification. For example, the circuit of the present invention can also be used to provide more reliable and safe low flow anesthesia, and its use can also significantly reduce the number of circuits used and disposed of, both of which lead to significant safety and environmental benefits. In addition, there has been a long-felt need for an adjustable length circuit that can retain the angle, shape and conformation to which the circuit is manipulated and can be used with spontaneous and assisted ventilation. Despite pleated tubing being available for over 20 years, and the teaching of unilimb circuits for over 35 years, no one has disclosed a unilimb circuit combining the above features taught by the present invention. The significant inventive merit of the present invention is also shown by the commercial success achieved by the present invention; there has been a significant increase in sales over time since the circuit of the present invention became available to the anesthesia practitioners. Such data has been reported to me by King Systems Corporation of Indiana (i.e., the company selling the circuit).

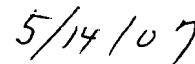
11. In summary, one of ordinary skill in the art, e.g., practicing health care providers that use breathing circuits and manufacturers thereof, would not find the present invention in or obvious from the prior art since *inter alia* there is no teaching or suggestion in the prior art that a circuit comprising pleated tubing can provide spontaneous and assisted ventilation and no teaching or suggestion to pick and choose components of the different prior art teachings and to reassemble

them to form the present invention (in fact there are reasons in the prior art why one of skill in the art would not want to make such modifications to prior art circuits), the present invention has significant performance, cost, and environmental benefits in comparison to prior art circuits, and the present invention is being used in place of prior art circuits demonstrating commercial success.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Atsuo F. Fukunaga, M.D., Ph.D.



Date

132declF3